

### **Remarks**

Claims 15-20 are currently pending in the application. Claims 1-14 have been cancelled as being drawn to a non-elected invention, without prejudice to the filing of one or more divisional applications directed to the subject matter thereof.

Claim 15 has been amended to more particularly point out that the annular continuous sealing zone is directly adjacent to and in continuous abutting contact with an entire outer circumferential edge of the inert film. Further, claim 16 has been amended to conform to the amendment to claim 15. Currently amended claims 15 and 16 are at least supported by Figure 11 and specification paragraphs [0005], [0010] and [0044].

The specification has been amended to include a description of "section 6b" and to reduce the number of words in the abstract. Support for these amendments can be found in original specification paragraph [0046], Figure 9 and the original abstract.

Accordingly, no new matter has been added and entry of the amendments is respectfully requested.

### **Information Disclosure Statements**

The Examiner noted that the Information Disclosure Statement (IDS), filed November 12, 2003, did not include legible copies of several foreign documents listed on the associated Form PTO/SB/08A. Applicant has attached hereto a copy of the November 12, 2003 Form PTO/SB/08A that lists the three foreign documents that are not initialed by the Examiner and legible copies of each of the non-initialed documents, as follows:

1. GB 593,531;
2. DE 1,952,899; and
3. FR 2,074,704.

Based on the above and the attached references, Applicant respectfully requests that the Examiner review the attached documents, initial the attached copy of Form PTO/SB/08A from the November 12, 2003 IDS and return the initialed Form PTO/SB/08A with any response to this Amendment, acknowledging receipt and review of the documents. No fee is due in connection with this resubmission, since the allegedly missing references were in fact previously received by the USPTO, as indicated by the post card receipt (copy enclosed) of November 12, 2003.

Furthermore, a supplemental IDS (copy enclosed), with associated Form PTO/SB/08A, was filed on April 8, 2004, as indicated on a post card receipt (copy enclosed). This supplemental IDS was filed because a reference was cited in a German Office Action, dated April 19, 2002, concerning a counterpart German application. No fee was believed to be due in connection with the filing of this supplemental IDS since it was filed before the mailing of the first Office Action on the merits. However, the Examiner has failed to consider this supplemental IDS. Applicant also notes that this supplemental IDS does not appear in the Image File Wrapper. Based on the above and the attached documents, Applicant respectfully requests that the Examiner review the cited U.S. reference, initial the attached copy of Form PTO/SB/08A from the April 8, 2004 supplemental IDS and return the initialed Form PTO/SB/08A with any response to this Amendment, acknowledging receipt and review of the cited reference

#### **Objections to the Drawings**

The Examiner has objected to the drawings as failing to comply with 37 C.F.R. § 1.84(p)(5) because they include the following reference character not mentioned in the description: “6b.” In accordance with the Examiner’s comments, specification paragraph [0046] has been amended to include reference character “6b”. In view of this amendment to the specification, Applicant respectfully submits that the drawings are in full compliance with the requirements. Applicant respectfully requests that the objection to the drawings be withdrawn.

#### **Objection to the Specification**

The Examiner has objected to the specification because the abstract is too long. In accordance with MPEP § 608.01(b), Applicant has amended the abstract to be less than 150 words. In view of this amendment, Applicant respectfully submits that the specification is in full compliance with the requirements. Applicant respectfully requests that the objection to the specification be withdrawn. In addition, the title of the invention has been amended to conform to the presently pending claims.

#### **Claim Rejections**

The Examiner has rejected claims 15-20 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 2,895,773 (McConnaughey) in view of European Patent No. 0148426 (Pharma Gummi). The Examiner acknowledges that McConnaughey fails to disclose a piston

section being enclosed in a cap-shaped inert film where the film comprises a fluorinated polymer film. The Examiner relies upon Pharma Gummi to teach a piston section of the piston stopper enclosed in a cap-shaped inert film comprising a fluorinated polymer film. The rejection of amended claim 15, and claims 16-20 depending therefrom, is respectfully traversed.

Referring to Fig. 3, McConnaughey discloses a piston cap 310 for a plunger head 320 which is placed inside a cylindrical barrel 330. The piston cap 310 is comprised of external annular ridges 302a, 302b and a free floating ring 302c. Further, a first intermediate groove 303a is located between the first external annular ridge 302a and the free floating ring 302c and a second intermediate groove 303b is located between the second external annular ridge 302b and the free floating ring 302c.

Referring to Fig. 18, Pharma Gummi discloses a piston 33 for use in a pharmaceutical syringe. The piston 33 is comprised of three radially protruding sealing bulges 34, 35, 36. The first sealing bulge 34 is sheathed with a fluorinated polymer film 8 which is undetachably connected to the rubber-elastic material of the piston 33.

Assuming, *arguendo*, that McConnaughey is properly combinable with Pharma Gummi, the proposed combination would fail to disclose Applicant's invention as claimed in amended claim 15.

Claim 15, as amended, recites, *inter alia*,

*the sealing section (10) has on its outer circumference an annular continuous sealing zone (13) directly adjacent to and in continuous abutting contact with an entire outer circumferential edge of the inert film (9').*

McConnaughey fails to disclose an annular continuous sealing zone directly adjacent to and in continuous abutting contact with an entire outer circumferential edge of the inert film or piston section. The Examiner defined the first external annular ridge 302a as the piston section and the free floating ring 302c as the annular continuous sealing zone in the Office Action. The free floating ring 302c is not directly adjacent to and is not in continuous abutting contact with an entire outer circumferential edge of the first external annular ridge 302a. Conversely, the free floating ring 302c disclosed by McConnaughey is separated from the first external annular ridge 302a by the first intermediate groove 303a. Due to this separation, the free floating ring 302c is

not directly adjacent to the first external annular ridge 302a and is not in continuous abutting contact with an entire outer circumferential edge of the first external annular ridge 302a.

Pharma Gummi does not make up for this deficiency. Pharma Gummi fails to teach an annular continuous sealing zone directly adjacent to and in continuous abutting contact with an entire outer circumferential edge of the inert film. Assuming, *arguendo*, that the second sealing bulge 35 taught by Pharma Gummi is an annular continuous sealing zone 13 as disclosed in the instant application, the second sealing bulge 35 is separated from the inert film by a groove 43. Therefore, due to this separation, the second sealing bulge 35 is not directly adjacent to the inert film and is not in continuous abutting contact with an entire outer circumferential edge of the inert film.

Since Pharma Gummi does not teach an annular continuous sealing zone directly adjacent to and in continuous abutting contact with an entire outer circumferential edge of an inert film, it could not have been obvious to one of ordinary skill in the art to create such a structure in McConnaughey. As described in paragraph [0007] of the instant application, Applicant notes that the first sealing bulge 34 sheathed with the inert film 8, as taught by Pharma Gummi, is a relatively poor seal to prevent medication from seeping into the groove 43 between the first and second sealing bulges 34, 35. Combining this teaching of Pharma Gummi with the structure disclosed by McConnaughey does not accomplish the same result as that of the instant application, namely reliably preventing contact between the contents in the syringe and the uncoated sealing section. Applicant's invention, as recited in amended claim 15, provides that an annular continuous sealing zone (13) is directly adjacent to and in continuous abutting contact with an entire outer circumferential edge of an inert film, thus avoiding that medication can seep into groove 12.

McConnaughey in view of Pharma Gummi fails to disclose each and every element of amended claim 15. Claims 16-20 are dependent on claim 15 and are therefore patentable over McConnaughey in view of Pharma Gummi for at least the same reasons discussed above. Applicant respectfully submits that claim 15, and claims 16-20 depending therefrom, are not unpatentable over McConnaughey in view of Pharma Gummi, and requests that the rejection under 35 U.S.C. § 103(a) be withdrawn

## CONCLUSION

In view of the foregoing Amendment and remarks, Applicant respectfully submits that the present application, including claims 15-20, is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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(Date)

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Encl: Replacement Page 21 (Abstract of the Disclosure)